PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MERL/20401740/JW/mt	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. **PCT**/SG2004/000407	International filing date *(day/month/year)* 13 December 2004	Priority date *(day/month/year)* 31 March 2004

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

A61F 2/06 (2006.01)

Applicant

MERLIN MD PTE LTD et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of **4** sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[X]	Box No. VI	Certain documents cited
[X]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27 January 2006	24 February 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **Sue Thomas** Telephone No. (02) 6283 2454

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SG2004/000407

Box No. I Basis of the report

1. With regard to the **language,** this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1-18** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[X] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **19-22** received by this Authority on 27 January 2006 with the letter of 27 January 2006
pages* received by this Authority on with the letter of

[X] the drawings: pages **1/10-10/10** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [X] The amendments have resulted in the cancellation of:

[ ] the description, pages
[X] the claims, Nos. nil, page 23
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-38**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-38**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-38**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The invention is a medical device for insertion into a bodily vessel for treating an aneurysm, the device including an expandable, permeable and porous membrane positioned proximal to the aneurysm, the pores of the membrane and ratio of surface material to pores being sized to prevent blood supply to the aneurysm, and allow blood supply to perforators or microscopic branches of arteries to improve healing of the bodily vessel.

The nearest prior art of WO 2002/069783 A2 provides an expandable permeable membrane which isolates the aneurysm but is not sized to allow a blood supply to perforators or microscopic branches of arteries to improve healing of the vessel.

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International application No.
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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
EP 1550477 A1	6 July 2005	20 August 2003	23 August 2003

The document EP 1550477 A1 was filed before the priority date of the present application and published after the priority date of the present application. EP 1550477 provides a medical device for insertion into a bodily vessel for treating an aneurysm, the device including an expandable, permeable and porous membrane over the entire device, with membrane pores of a size to allow passage and growth of endothelial cells to inhibit the formation of thrombus. The size, see page 6, includes pores too large for the prevention of blood flow to the aneurysm required by the present application. Consequently, the novel and inventive feature of the present invention is not provided by this document.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 4 (as amended 27 January 2006) and pages 3, 9, 12 and 15 of the description express some dimensions in inches instead of the required metric measure.

WE CLAIM:

1. A medical device for insertion into a bodily vessel to treat an intracranial aneurysm, the device comprising:

a mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and

a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable device, said membrane being positioned proximal to the aneurysm and obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to the mechanically expandable device to maintain the position of the membrane relative to the mechanically expandable device when expanded to the second position;

wherein the membrane is permeable and porous, the size of the pores of the membrane and the ratio of the material surface area of the membrane being such that blood supply to perforators and/or microscopic branches of main brain arteries is permitted to improve healing of the bodily vessel but blood supply to the aneurysm is prevented.

2. The device of claim 1, wherein the distance between adjacent pores is from about 40 to 100 microns.

3. The device of claim 1, wherein the membrane is made of a biocompatible and elastomeric polymer.

4. The device of claim 1, wherein the membrane has a thickness of about 0.0005 to 0.005".

5. The device of claim 1, wherein the ratio of the material surface area of the membrane is from about 25 to 75%.

6. The device of claim 1, wherein the membrane has pores between 20 to 100 microns in size.

7. The device of claim 1, wherein the membrane is made from polymeric material or biodegradable material.

8. The device of claim 7, wherein the biodegradable material forms multiple sub-layers mixed with drugs or reagents.

9. The device of claim 1, wherein the membrane is capable of isotropic expansion.

10. The device of claim 1, wherein the membrane is disposed on the exterior surface of the device.

11. The device of claim 1, wherein the membrane completely surrounds the device.

12. The device of claim 1, wherein the membrane circumferentially surrounds a portion of the device.

13. The device of claim 1, wherein the membrane covers a portion of the device.

14. The device of claim 1, wherein the membrane is non-porous and non-permeable to prevent blood circulation to the aneurysm.

15. The device of claim 14, wherein the membrane is made from a solid polymer.

16. The device of claim 1, wherein the membrane has fabricated pores between 20 to 100 microns in size.

17. The device of claim 16, wherein the pores are fabricated by laser drilling.

18. The device of claim 16 or 17, wherein the distance between the pores is less than 100µm.

19. The device of claim 1, wherein the membrane comprises a plurality of polymeric strips secured to the mechanically expandable device

20. The device of claim 19, wherein the strips are less than 0.075mm and the distance between adjacent strips is less than 100µm.

21. The device of claim 1, wherein the membrane comprises a mesh secured to the mechanically expandable device.

22. The device of claim 21, wherein spaces of the mesh is less than 100µm and the width of the meshing is between 0.025 to 0.050mm.

23. The device of claim 1, wherein the aneurysm is any one from the group consisting of: a regular size, giant or wide neck aneurysm having an aneurysm neck greater than 4 millimeters or a dome to neck ratio greater than 2, berry aneurysm, CC fistula and fusiform aneurysm.

24. The device of claim 1, wherein the mechanically expandable device comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween.

25. The device of claim 1, wherein the mechanically expandable device is self-expandable or balloon expandable.

26. The device of claim 1, wherein the mechanically expandable device is a stent.

27. The device of claim 24, wherein the membrane is supported by the generally tubular structure and is attached to at least one strut.

28. The device of claim 26, wherein the membrane is tubular having a diameter similar to a nominal initial diameter of the stent; and wherein the membrane is disposed onto the outer surface of the stent or introduced by dip coating or spraying between the struts of the stent.

29. The device of claim 26, wherein the membrane is a segment of a tubular structure disposed onto a portion of the outer surface of the stent.

30. The device of claim 8, wherein the at least one reagent is in any one form selected from the group consisting of: solid tablet, liquid and powder.

31. The device of claim 1, wherein at least one radiopaque marker is provided on the mechanically expandable device to improve visibility of the device during and after insertion.

32. The device of claim 31, wherein the at least one radiopaque marker is made from gold or platinum.

33. The device of claim 31, wherein center radiopaque markers and end radiopaque markers are provided on the mechanically expandable device.

34. A medical device for treating a bifurcation or trifurcation intracranial aneurysm between at least two bodily vessels, the device comprising:

a first mechanically expandable device for inserting into a first vessel;

a second mechanically expandable device for inserting into a second vessel;

each mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and

a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable devices, said membrane being positioned proximal to the aneurysm and obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to each mechanically expandable device to maintain the position of the membrane relative to the mechanically expandable devices when expanded to the second position;

wherein the membrane is permeable and porous, the size of the pores of the membrane and the ratio of the material surface area of the membrane being such that blood supply to perforators and/or microscopic branches of main brain arteries is permitted to improve healing of the bodily vessel but blood supply to the aneurysm is prevented.

35. A method of making a medical device according to claim 1, the method comprising:

disposing the generally tubular structure on a mandrel; and

disposing the membrane onto the outer surface of the mechanically expandable device.

36. A method of making a medical device according to claim 24, the method comprising:

disposing the generally tubular structure on a mandrel; and

incorporating the membrane between the struts of the stent.

37. The method of claim 35 or 36, wherein the disposing is any one selected from the group consisting of: spraying, suture, lamination, adhesion, heat and dip coating.

38. The device of claim 26, wherein the stent is delivered to the aneurysm by a delivery catheter.